### AMENDMENTS TO THE CLAIMS:

Please amend the claims as follows:

Claims 1-91. (Canceled)

92. (Currently Amended) A pharmaceutical formulation <u>suitable for parenteral</u> administration comprising:

- (i) an amphiphilic drug; and
- (ii) a short-chain sphingolipid selected from compounds of the following

#### formula:

wherein:

R<sup>1</sup> is independently:

an O-linked saccharide group; or

an O-linked polyhydric alcohol group;

or:

R<sup>1</sup> is independently:

an O-linked (optionally N-(C1-4alkyl)-substituted

amino)-C1-6alkyl-phosphate group; or

an O-linked (polyhydric alcohol-substituted)-C<sub>1-6</sub>alkyl-

phosphate group;

R2 is independently C3-9alkyl,

and is independently unsubstituted or substituted;

R3 is independently C7-19alkyl,

and is independently unsubstituted or substituted;

R4 is independently -H, -OH, or -O-C<sub>1-4</sub>alkyl;

R<sup>N</sup> is independently -H or C<sub>1-4</sub>alkyl;

the bond marked with an alpha  $(\alpha)$  is independently a single bond or a double bond:

if the bond marked with an alpha (a) is a double bond, then  $\mathsf{R}^5$  is -H;

if the bond marked with an alpha (a) is a single bond, then  $\ensuremath{\mathsf{R}}^5$  is -H or -OH;

the carbon atom marked (\*) is independently in an R-configuration or an  $\ \,$ 

## S-configuration;

the carbon atom marked (\*\*) is independently in an R-configuration or an S-configuration;

with the proviso that when  $R^1$  is an O-linked saccharide group which is derived from galactopyranose, then  $R^1$  is D-galactopyranosyl- $\beta 1$ -;

and pharmaceutically acceptable salts thereof.

Claim 93. (Canceled)

94. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said drug is an anthracycline.

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95. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said drug is selected from: doxorubicin, idarubicin, epirubicin, aclarubicin, mitrozantrone, and daunorubicin, and salts thereof.

96. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said drug is doxorubicin or doxorubicin hydrochloride.

 (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said drug is an alkaloid.

98. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said drug is selected from: topotecan and camptothecin.

99. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $\mathsf{R}^2$  is linear.

100. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>2</sup> is linear; and has from 0 to 3 carbon-carbon double bonds.

101. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^2$  is unsubstituted or substituted with from 1 to 3 substituents selected from  $C_1$ -alkyl, -OH,  $C_1$ -alkoxy, -C(=O)OH, and -C(=O)O- $C_1$ -alkyl.

102. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^2$  is -(CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, wherein n is an integer from 4 to 8.

103. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^2$  is -(CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, wherein n is an integer from 6 to 8.

- 104. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^2$  is -(CH<sub>2</sub>)<sub>8</sub>CH<sub>3</sub>.
- 105. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein the bond marked alpha is a double bond and R<sup>5</sup> is -H.
- 106. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein the bond marked alpha is a single bond; and R<sup>5</sup> is -H.
- 107. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein the bond marked alpha is a single bond; and R<sup>5</sup> is -OH.
- 108. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $\mathbb{R}^3$  is linear.
- 109. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R³ is linear: and has from 0 to 3 carbon-carbon double bonds.
- 110. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^3$  is unsubstituted or substituted with from 1 to 3 substituents selected from  $C_1$ -4alkyl, -OH,  $C_1$ -4alkoxy.
- 111. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $\mathbb{R}^3$  is -(CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, wherein n is an integer from 8 to 16.
- 112. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^3$  is -(CH<sub>2</sub>)<sub>12</sub>CH<sub>3</sub>.

113. (Previously Presented) A pharmaceutical formulation according to claim 92.

#### wherein the moiety:

$$\left\{ \begin{array}{c} \alpha \\ R^5 \end{array} \right\}$$

is selected from the following:

-(CH<sub>2</sub>)<sub>8</sub>-CH<sub>3</sub>;

-(CH2)10-CH3;

-(CH<sub>2</sub>)<sub>12</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>14</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>7</sub>-CH=CH-(CH<sub>2</sub>)<sub>5</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>16</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>7</sub>-CH=CH-(CH<sub>2</sub>)<sub>7</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>9</sub>-CH=CH-(CH<sub>2</sub>)<sub>5</sub>-CH<sub>3</sub>;

-(CH2)7-[CH=CH-CH2]2-(CH2)3-CH3;

-(CH<sub>2</sub>)<sub>7</sub>-[CH=CH-CH<sub>2</sub>]<sub>3</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>4</sub>-[CH=CH-CH<sub>2</sub>]<sub>3</sub>-(CH<sub>2</sub>)<sub>3</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>7</sub>-[CH=CH]<sub>3</sub>-(CH<sub>2</sub>)<sub>3</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>18</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>6</sub>-[CH=CH-CH<sub>2</sub>]<sub>2</sub>-(CH<sub>2</sub>)<sub>6</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>3</sub>-[CH=CH-CH<sub>2</sub>]<sub>3</sub>-(CH<sub>2</sub>)<sub>6</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>3</sub>-[CH=CH-CH<sub>2</sub>]<sub>4</sub>-(CH<sub>2</sub>)<sub>3</sub>-CH<sub>3</sub>;

-(CH<sub>2</sub>)<sub>20</sub>-CH<sub>3</sub>;

analogs of the foregoing wherein the left-most -( $CH_2$ )<sub>2</sub>- is replaced with -CH=CH-; and

analogs of the foregoing wherein the left-most -(CH $_2$ )- is replaced with -CH(OH)-.

- 114. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>4</sup> is -H, -OH, -OMe, -OEt, -O(iPr), -O(nPr), -O(nBu), -O(iBu), -O(sBu), or -O(tBu).
- 115. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^4$  is -OH.
- 116. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^N$  is -H, -Me, or -Et.
- 117. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein the carbon atoms marked (\*) and (\*\*) have a configuration as shown in the following formula:

$$R^{N}$$
 $R^{1}$ 
 $R^{4}$ 
 $R^{5}$ 
 $R^{5}$ 

118. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein  $R^1$  is an O-linked saccharide group.

- 119. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>1</sup> is an O-linked mono-, di-, or tri-saccharide group.
- 120. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R¹ is comprises a group or groups selected from:

arabinose, lyxose, ribose, xylose,

allose, altrose, glucose, mannose, gulose, idose, galactose, and

talose;

and derivatives thereof.

121. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>1</sup> is an O-linked mono-, di-, or tri-saccharide group comprising a group or groups selected from:

arabinose, lyxose, ribose, xylose,

allose, altrose, glucose, mannose, gulose, idose, galactose, talose,

sucrose, maltose, lactose, cellobiose, galabiose,

globotriaose, isoglobotriaose, mucotriaose, lactotriaose,

neolactotriaose gangliotriaose, galatriaose, mollutriaose, and antrotriaose;

and derivatives thereof.

122. (Currently Amended) A pharmaceutical formulation according to claim 120, wherein said saccharide group derivatives are selected from deoxy, di-deoxy, di-deoxy-di-dehydro, methoxy [[(-OKe)]], acetoxy [[(-OC(=O)Me)]], carboxylic acid [[(-C(=O)OH)]],

sulfuric acid [[(-OSO<sub>3</sub>H)]], amino-deoxy [[(-NH<sub>2</sub>)]], N-acetyl-amino-deoxy

[[(-NHC(=O)Me)]], or N-sulfo-amino-deoxy-(-NHS(O)2OH) derivatives.

123. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said short-chain sphingolipid has the following formula (C<sub>8</sub>-GlcCer):

124. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said short-chain sphingolipid has the following formula:

(Currently Amended) A pharmaceutical formulation <u>comprising:according-to-claim-92</u>,

#### (i) a drug; and

(ii) a short-chain sphingolipids selected from compounds of the following formula

wherein:

R1 is independently an O-linked polyhydric alcohol group

R2 is independently C3.9alkyl.

and is independently unsubstituted or substituted;

R3 is independently C7-19alkyl,

and is independently unsubstituted or substituted;

R<sup>4</sup> is independently -H, -OH, or -O-C<sub>1-4</sub>alkyl;

R<sup>N</sup> is independently -H or C<sub>1-4</sub>alkyl;

the bond marked with an alpha (a) is independently a

single bond or a double bond;

if the bond marked with an alpha (α) is a double bond, then R<sup>5</sup> is -H;

if the bond marked with an alpha (α) is a single bond, then R<sup>5</sup> is -H or -OH;

the carbon atom marked (\*) is independently in an R-configuration or an

S-configuration;

the carbon atom marked (\*\*) is independently in an R-configuration or an S-configuration:

and pharmaceutically acceptable salts thereof.

- 126. (Previously Presented) A pharmaceutical formulation according to claim 125, wherein R<sup>1</sup> comprises a group selected from: ethanediol (glycol), propanediol, butanediol, glycerol, and erythritol.
- 127. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>1</sup> is:

an O-linked (optionally N-(C<sub>1-4</sub>alkyl)-substituted amino)-C<sub>1-6</sub>alkyl-

phosphate group; or

an O-linked (polyhydric alcohol-substituted)-C<sub>1-6</sub>alkyl-phosphate group.

128. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R<sup>1</sup> is:

wherein:

q is an integer from 0 to 5;

Q is: -NH<sub>2</sub>, -NHR<sup>a</sup>, -NR<sup>a</sup><sub>2</sub>, or -NR<sup>a</sup><sub>3</sub><sup>+</sup>; or:

Q is a polyhydric alcohol group, linked via an oxygen atom;

each  $R^a$  is linear or branched saturated  $C_{1-4}$ alkyl.

129. (Previously Presented) A pharmaceutical formulation according to claim 92,

# wherein R1 is:

$$\begin{array}{c|c}
R^{a} & + \\
R^{a} & N
\end{array}$$

wherein:

 ${\bf q}$  is an integer from 0 to 5; and

each Ra is a C1-4alkyl group.

130. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein R¹ is:

131. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said short-chain sphingolipid has the following formula ("C<sub>e</sub>-SM"):

132. (Previously Presented) A pharmaceutical formulation according to claim 92, wherein said short-chain sphingolipid has the following formula ("3-O-methyl-C<sub>8</sub>-SM"):

- 133. (Previously Presented) A pharmaceutical formulation according to claim 128, wherein Q is a polyhydric alcohol group, linked via an oxygen atom.
- 134. (Previously Presented) A pharmaceutical formulation according to claim 133, wherein Q comprises a group selected from: ethanediol (glycol), propanediol, butanediol, glycerol, and erythritol.

Claim 135. (Canceled)

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Amendment

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136. (Previously Presented) A pharmaceutical formulation according to claim 92,

wherein the pharmaceutical formulation is a liposomal pharmaceutical formulation.

137. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 136, wherein the liposomes of the liposomal pharmaceutical formulation are

prepared using a mixture of lipids comprising, at least, vesicle-forming lipids and said

short-chain sphingolipid.

138. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 137, wherein said mixture of lipids comprises phospholipids and said short-

chain sphingolipid.

139. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 137, wherein said mixture of lipids comprises phospholipids, cholesterol, and

said short-chain sphingolipid.

140. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 137, wherein said mixture of lipids comprises phosphatidylcholines, cholesterol.

and said short-chain sphingolipid.

141. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 137, wherein said mixture of lipids comprises fully hydrogenated soy

phosphatidylcholine (HSPC), cholesterol, and said short-chain sphingolipid.

142. (Previously Presented) A liposomal pharmaceutical formulation according

to claim 137, wherein said mixture of lipids comprises dipalmitoyl-phosphatidylcholine

(DPPC), cholesterol, and said short-chain sphingolipid.

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- 143. (Previously Presented) A liposomal pharmaceutical formulation according to claim 137, wherein said mixture of lipids additionally comprises a vesicle-forming lipid which is derivatized with a polymer chain.
- 144. (Previously Presented) A liposomal pharmaceutical formulation according to claim 137, wherein said mixture of lipids additionally comprises a phosphatidylethanolamine (PE) which is derivatized with polyethyleneglycol (PEG).
- 145. (Previously Presented) A liposomal pharmaceutical formulation according to claim 137, wherein said mixture of lipids additionally comprises N-(carbonylmethoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine sodium salt (MPEG2000-DSPE).
- 146. (Currently Amended) Caelyx® or Doxil® liposomes post-inserted with a short-chain sphingolipid selected from compounds of the following formula:

wherein:

R1 is independently:

an O-linked saccharide group; or

an O-linked polyhydric alcohol group;

or:

R1 is independently:

an O-linked (optionally N-(C<sub>1-4</sub>alkyl)-substituted amino)-C<sub>1-6</sub>alkyl-phosphate

group; or

an O-linked (polyhydric alcohol-substituted)-C<sub>1-6</sub>alkyl-phosphate group;

R2 is independently C3-9alkyl,

and is independently unsubstituted or substituted:

R<sup>3</sup> is independently C<sub>7-19</sub>alkyl,

and is independently unsubstituted or substituted;

R<sup>4</sup> is independently -H, -OH, or -O-C<sub>1-4</sub>alkyl;

 $\ensuremath{\mathsf{R}}^N$  is independently -H or  $C_{1\text{--}4}alkyl;$ 

the bond marked with an alpha  $(\alpha)$  is independently a single bond

or a double bond:

if the bond marked with an alpha ( $\alpha$ ) is a double bond, then  $R^5$  is -H;

if the bond marked with an alpha ( $\alpha$ ) is a single bond, then R<sup>5</sup> is -H or -OH;

the carbon atom marked (\*) is independently in an R-configuration or an

S-configuration;

the carbon atom marked (\*\*) is independently in an R-configuration or an

S-configuration;

with the proviso that when  $R^1$  is an O-linked saccharide group which is derived from galactopyranose, then  $R^1$  is D-galactopyranosyl- $\beta 1$ -;

and pharmaceutically acceptable salts thereof.

Claims 147-151. (Canceled)